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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,577	07/19/2005	Takanori Uchida	UCHIDA=9	6886
1444 7590 09/10/2010 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER KIM, TAEYOON	
			ART UNIT 1651	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,577	Applicant(s) UCHIDA ET AL.	
	Examiner Taeyoon Kim	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 17-21, 24-29, 32-34, 36-38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 17-21, 24-29, 32-34, 36-38 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment and response filed on 7/12/2010 has been received and entered into the case.

Claims 1-13, 15, 16, 22, 23, 30, 31, 35, 39 and 40 are canceled, claim 41 is newly added, and claims 14, 17-21, 24-29, 32-34, 36-38 and 41 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

The claim rejection under 35 U.S.C. § 112 has been withdrawn.

Claim Objections

Claim 36 is objected to because of the following informalities: The instant claim starts with the term "In". It would be appropriate to start the claim with "A hemostatic material..." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 and 27 recites the limitation "Factor XIII" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 17-21, 24-29, 32-34, 36-38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugitachi et al. (of record) in view of Greenawalt et al. (of record) and Gunze (JP 63095041; same as the English translation of JP1993-018527 submitted on 11/27/2007; Abstract only).

Sugitachi et al. teach an absorbable material such as polyglycolic acid (PGA) comprising thrombin, and a process of making such is by dipping the material in saline solution of thrombin and then lyophilized (see Examples 2 and 6).

Sugitachi et al. also teach the absorbable material being non-woven fabric (col. 1, lines 49-55).

Although Sugitachi et al. do not teach the material comprising fibrinogen, it would have been obvious to a person of ordinary skill in the art to use fibrinogen separately or together with thrombin/PGA fibers of Sugitachi et al., because it is notoriously well known in the art that the role of thrombin is to activate fibrinogen to fibrin to form a fibrin network, and fibrinogen is commonly added to thrombin or visa versa. For example, a fibrin sealant, TisseelTM, disclosed by Greenawalt et al. comprises two-component system: fibrinogen component and thrombin component, and fibrinogen component comprising Factor XIII, to be mixed before the use the system (see column 1, lines 20-30). Thus, a person of ordinary skill in the art would recognize

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that additional fibrinogen comprising Factor XIII taught by Greenawalt et al. applied to the thrombin/PGA fabric of Sugitachi et al. before the use of thrombin/PGA fabric to a wound site would enhance and/or facilitate the formation of fibrin network, instead of utilizing fibrinogen present in the plasma of a patient being treated with a reasonable expectation of success.

Furthermore, since the use of fibrinogen along with thrombin is well known in the art as a hemostatic composition, it would have been obvious to a person of ordinary skill in the art to try fibrinogen applied to the thrombin/PGA fabric of Sugitachi et al. prior to the use of the fabric to a wound site to stop bleeding with a reasonable expectation of success in using the thrombin/PGA fabric along with fibrinogen/Factor XIII of Greenawalt et al.

It is well known in the art that a nonwoven felt, Neoveil from Gunze, Inc., is considered as a suitable PGA fabric to be used as the non-woven fabric of Sugitachi et al. Gunze, which is the same as the JP application (JP 1993-018527) submitted by Applicant as a part of the amendment/remark on 11/27/2007 to the OA filed on 6/1/2007, teaches that non-woven, needle-punched PGA pledget which is decomposed and absorbed into living body, and thus high affinity to living body can be attained and no side effect or undesirable effect to living body (see abstract), and thus, a person of ordinary skill in the art would recognize that the nonwoven needle punched PGA fabric/pledget would be a suitable alternative and/or equivalent for the non-woven PGA fabric used in the hemostatic and wound healing composition of Sugitachi et al.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to substitute the nonwoven PGA fabric of Sugitachi et al. with the nonwoven felt, Neoveil, taught by JP 189579. In addition, Applicant admitted that the nonwoven PGA felt formed by needle-punching as taught by JP 189579 is Neoveil used in the Examples of

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the current application.

With regard to the elastic property of the hemostatic material of the current invention, the non-woven needle punched PGA fabric of Neoveil taught by JP 189579 would have inherently possessed the same property as the claimed invention.

M.P.E.P. § 2112 recites, “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.” *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

With regard to the hemostatic kit of the current invention, Greenawalt et al. teach a hemostatic kit comprising multiple hemostatic compositions in a separate package. It is well known in the art hemostatic compositions are packaged in a form of kit as shown by TisseelTM (see column 1, lines 20-22; column 6, lines 51-59).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try to prepare the hemostatic materials of Sugitachi et al. (i.e. thrombin/PGA) along with fibrinogen/Factor XIII of TisseelTM disclosed by Greenawalt et al. in a format of a kit. See *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007).

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With regard to the new limitation directed to "having sufficient flexibility and elasticity to ensure sticking to an affected area of approximately any shape", it is considered that the limitation is resulted from the use of a particular nonwoven PGA fabric, that is Neoveil, rather than the results being obtainable from any active step to be carried out. Since Neoveil is well known in the art as discussed above, and a person of ordinary skill in the art would recognize Neoveil as a suitable non-woven PGA fabric for the composition of Sugitachi et al., the newly introduced limitation directed to the property of the PGA fabric would be inherently met by the use of Neoveil in the composition of Sugitachi et al. in view of JP 189579.

With regard to the limitation of new claim 41, the step of applying the fabric against a wound suffering projectile bleeding is not considered as a step for the method of preparing the claimed nonwoven synthetic fabric holding thrombin and fibrinogen. Rather it is considered as the method of using the fabric of the current invention. Nevertheless, the nonwoven fabric taught by the references, Neoveil holding thrombin, fibrinogen and Factor XIII, is intended for stopping bleeding, and thus, it would have been obvious to a person of ordinary skill in the art to use the hemostatic composition of the references for a wound having projectile bleeding.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

In the response, applicant alleged that Greenawalt teaches away from the Tisseel system relied upon in the rejection. This argument is not persuasive since the claim rejection is not particularly relied on Tisseel system, rather the teaching of Greenawalt et al. is used for the use of fibrinogen in the hemostatic composition along with thrombin. As discussed, the composition

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made by the process of Sugitachi et al. contains thrombin and Factor XIII, and the composition of Sugitachi et al. is intended for a hemostatic material. Thus, it would have been obvious to a person of ordinary skill in the art to use fibrinogen to the composition of Sugitachi et al. by showing that various different type of hemostatic materials including Tisseel contain both thrombin and fibrinogen, which are activated before the use of the hemostatic materials. The claim rejection is not based on the use of Tisseel system in the composition of Sugitachi et al. Even if it is considered that Tisseel system is being used in the composition of Sugitachi et al., the disadvantage of water-like fluidity of the components, however, would not teach away a person of ordinary skill in the art to use thrombin and fibrinogen in the composition of hemostatic materials such as the composition of Sugitachi et al. since it is well known in the art that these two components (thrombin and fibrinogen) are required for the formation of fibrin network.

Applicant further alleged that there is no reasonable expectation of the effects produced according to the present invention as shown in Table 1 and 2 of the specification. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., effects shown in Table 1 and 2) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, since the method of making nonwoven synthetic fabric holding thrombin, fibrinogen, and Factor XIII utilizing particularly Neoveil taught by the references above, it

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would have been obvious to a person of ordinary skill in the art to consider that the materials taught by the references would have the same properties as the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 14 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 11/941,779.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications disclose a method of preparing nonwoven fabric comprising PGA holding thrombin by immersing the fabric into a saline or buffer solution containing thrombin, followed by lyophilizing the fabric. Although the claims of '779 application do not particularly teach a step of adding fibrinogen immediately prior to use of the thrombin-PGA fabric, it would have been obvious to a person of ordinary skill in the art to use fibrinogen

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because it is notoriously well known in the art that the role of thrombin is to activate fibrinogen to fibrin to form a fibrin network, and fibrinogen is commonly added to thrombin as a hemostatic purpose. Thus, a person of ordinary skill in the art would recognize that the method of '779 is directed to the making of intermediate product of non-woven fabric holding thrombin, which can be used for the final hemostatic materials in combination with fibrinogen. Therefore, it is considered that the claims of '779 application render the claim of instant application obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651